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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

July 2, 1999

WARNING LETTER
CIN-WL-99-287

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert C. McKernan
Operations Manager
Hess & Clark, Inc.
10 East 7th Street
Ashland, OH 44805

Dear Mr. McKernan:

The Food and Drug Administration conducted an inspection of your animal drug manufacturing facility located at the above address on May 24, 25, 27 and June 1, 2, 9, 1999. Our investigator documented significant deviations from the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals (Title 21 Code of Federal Regulations [CFR] Parts 210 and 211). These deviations cause your animal drug products such as NFZ Puffer, NFZ Wound Powder and 20% Sulfaquinoxaline Sodium Solution, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The deviations documented during the inspection included:

A. The current NFZ Wound Dressing Powder/Puffer batch records contain some compounding parameters which were not part of or documented in the batch records for the validation lots. This includes the speed setting for the mixer; mixing time of [redacted] in step 5; mixing time of [redacted] in step 7; and to use [redacted] of dry ice during the coarse grinding. Portions of previous batches were not added to any of the validation lots but their use is allowed for in the current batch record.

B. The current batch records did not always specify mix times, document process temperatures or document the weighing of ingredients.

C. The compounding of NFZ Wound Dressing, Lot 09273 did not follow the written instructions in the batch records. The second compounder did not check the weights of some ingredients.

D. The batch records for four lots of NFZ Wound Dressing did not indicate the additional amounts of NFZ and PEG 3250 that were added and how long, or even if, additional mixing was done to achieve a homogenous batch.

E. Inaccurate dates on some batch records have not been noticed during the batch record review.

F. Employee training is not documented.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder are being met.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include seizure and injunction.

Please notify this office within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the Food and Drug Administration, Compliance Branch, 6751 Steger Drive, Cincinnati, Ohio 45237 to the attention of Lawrence E. Boyd, Compliance Officer.

Sincerely

Mary L Womack for
Henry L. Fielden
District Director
Cincinnati District

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